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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,167	11/07/2000	Maurice Maloney	9369-161	8170

1059 7590 06/18/2003

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EXAMINER

LIU, SAMUEL W

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/707,167

Applicant(s)

MALONEY ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 20 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-28, 31, 32 and 34 is/are allowed.
- 6) ☒ Claim(s) 18, 20, 29, 30, 33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The response filed 6 March 2003 (Paper No. 10) as to deletion of claims 19 and 21, addition of new claims 34-35 and amendment of claims 18, 20 and 22, and Applicants' request for extension of time of three months have been entered. Thus, the pending claims 18, 20 and 22-35

are under examination to the extent that they are drawn to the elected invention.

Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

Terminal Disclaimer

The terminal disclaimer filed on 28 February 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. NO. 5856452 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

Claim Rejections - 35 USC § 102

The argument of the response filed 6 March 2003 (pages 5-6) is persuasive; thus the rejection under 35 U.S.C. 102 (a) is withdrawn.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 18, 20, 29-30 and 35 are rejected under the judicially created doctrine of the obviousness-type double patenting over Claims 1-2, 5, and 7-8 of US patent No. 6509453. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-2, 7, 16 and 19 of US Pat. No. 6509453 sets forth a method of separation of a target molecule from a sample (see claim 1) comprising contacting oil bodies with the sample containing target molecule that associates with the protein ligand (see claims 2 and 7), wherein the protein ligand is an antibody (see claims 16 and 19) not a protein (*i.e.*, oil body protein)

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naturally associated associate with the oil-body. The patent claims 1, 2, 7, 16 and 19 together is therefore an obvious variation of claims 29-30 of the current application.

Also, patent claim 11 of US Pat. No. 6509453 recites a target molecule is thrombin while the ligand molecule is protein A. Since thrombin is a protein, claim 10 is an obvious variation of claim 35 of the instant application which sets forth that the target molecule is a protein.

In addition, the patent claims are an obvious variation over claim 18 of the instant application because a method for the separation of a target molecule from *a sample* is an obvious variation of a method for the separation of a target molecule from *a cell*. Note that the biological sample encompasses cellular sample, e.g., cell per se. Further, the patent claim 16 is an obvious variation over claim 20 of the instant application because claim 16 sets forth that the protein ligand is an antibody.

It is therefore concluded that the claims of the present application are not patentably distinct from the claims of US Pat. No. 58566452.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional Rejection - Obviousness Type Double Patenting

Claim 29 of this application conflicts with claims 37, 41, 45 and 48 of Application No. 10260960. 37 CFR 1.78(b) provides that when two or more applications filed by the same

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applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 29 is provisionally rejected under the judicially created doctrine of double patenting over claims 37, 41, 45 and 48 of copending Application No. 10260960. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

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Claim 37 and its dependent claims 41, 45 and 48 of Application No. 10260960 together teach the limitation set forth in the application claim 29 which is directed to a method of separating a target molecule from a sample comprising contacting oil bodies with a protein ligand which associates with both the oil bodies and the target molecule and the target molecule-containing sample through the ligand molecule. The patent claim 37 sets forth a method of separating a target molecule (i.e., immunoglobulin) from a sample comprising contacting oil bodies with a sample that contains the target molecule, wherein the oil bodies associates with target molecule through a ligand (see the patent claim 41, which sets forth limitation for claim 37) that is a protein (see the patent claim 45, which further sets forth limitation for claim 37), and wherein the ligand is protein A (the patent claim 48, which sets forth limitation for claim 37). Note that since protein A is not oil body protein, the claims of Application No. 10260960 meet the limitation regarding "the protein ligand is not a protein that is normally associated with oil bodies" set forth in the application claim 29. Thus, claim 37 together with its dependent claims 41, 45 and 48 of Application No. 10260960 are an obvious variation of claim 29 of the instant application, and they are not patentably distinct from each other.

Conclusion

Claims 18, 20, 29-30, 33 and 35 are rejected, and claims 22-28, 31-32 and 34 are free from the prior arts.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

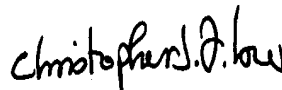
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The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.

June 8, 2003



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